

## PRE-APPEAL BRIEF

This pre-appeal brief is responsive to the Final Office Action dated June 23, 2009. In the application, claims 29 - 35 are pending and each claim stands rejected under 35 U.S.C. §103 based upon the combined teachings of Deem, U.S. Patent No. 6,558,400 ("Deem") with Adams et al., U.S. Patent Publication No. 2003/0132267 ("Adams"). Applicant respectfully requests reconsideration of the rejection of Claim 29 in view of the arguments below.

### Claim 29

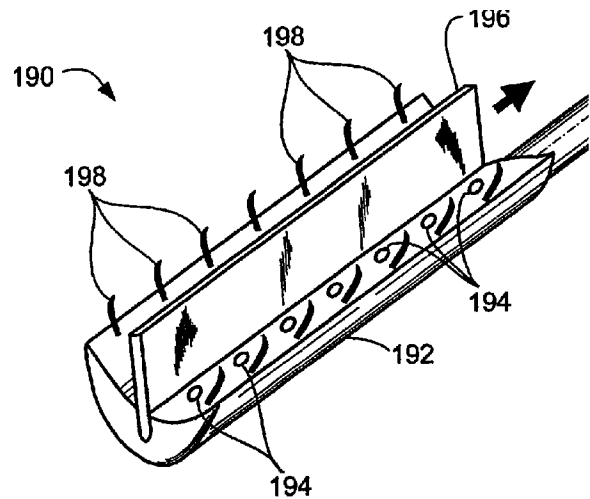
29. *A gastroplasty device, comprising:  
a cartridge assembly having a longitudinal axis, the cartridge assembly having a first tissue acquisition member pivotable about the longitudinal axis in relation to a second tissue acquisition member;  
each tissue acquisition member including a tissue receiving cavity sized to receive a fold of stomach tissue, the tissue receiving cavity being coupled to a vacuum port; and  
a stapler disposed on the first tissue acquisition member and the second tissue acquisition member for stapling the fold of stomach tissue.*

Claim 29 is directed to a gastroplasty device that includes first and second tissue acquisition members, each acquisition member including a tissue receiving cavity, and a stapler. The Office Action states: "Deem discloses the claimed device except for the first tissue acquisition member being pivotable about the longitudinal axis." The Office Action then states that it would have been obvious "to provide a pivotable first tissue acquisition member, as taught by Adams et al., to modify Deem in order to accommodate variable-sized tissue selections and since it was known in the art that pivotable tissue acquisition members facilitate grasping and apposition of tissue to ensure engagement of tissue." [Office Action, p. 3].

When the Applicant questioned the benefit of combining the references, the examiner stated in the Final Office Action that "the benefit having the tissue acquisition member of Deem being pivotable along a longitudinal hinge, as taught by Adams, would be allowing the member to accommodate variably-sized tissue sections." [O.A., p. 4]. Applicant in its Rule 116 Amendment questioned what this meant, as "variable-sized tissue" can be length (in the axial direction) or width (in the radial direction). In the axial direction, the size is governed by the number and spacing of the vacuum ports, and would be unaffected by having pivoting tissue acquisition members. In the radial direction, the "width" of the tissue section is controlled by the location of the staples with reference to the vacuum ports, with are also fixed whether the tissue

acquisition members are pivoting or non-pivoting. Deems' device (shown below) would not obtain a different **size** tissue section if the stapler of Adams were somehow incorporated into Deem's device as contended by the Office Action.

In response to Applicant's Rule 116 Amendment, an advisory action was entered by the Examiner which states that pivotable tissue acquiring members is "old," but still fails to explain what benefit would be achieved by the pivoting of the Deem device. The Examiner appears to have abandoned the "variable-sized tissue" argument but did not articulate any benefit in its place, other than its "old." However, the Supreme Court in *KSR International v. Teleflex*, 550 U.S. 398 (2007) warned against "slipping into the use of hindsight" and that there must be "an apparent reason to combine known elements in the fashion claimed by the patent (application) at issue." A rejection that the elements are "old" does nothing to prevent against prohibited hindsight and cannot form the basis of a *prima facie* obviousness rejection.



The Office Action also makes a statement that Adams, and specifically the seventh embodiment, teaches first and second tissue **acquisition members**. However, the cited paragraph 125 relied upon by the Office Action merely states that the stapler of Figures 21-25 has a "tissue receiving position." This would appear to be the "open" configuration where tissue can be received between the stapler and anvil. However, there is nothing that can "acquire" tissue and therefore the Office Action's statement that Adams teaches "tissue acquisition members" is incorrect. In response, the Advisory Action claims that the anvil of Adams engages tissue and therefore reads on this limitation. However, the claim does not call for "tissue engagement members," but rather tissue acquisition members. The fact that a surface (here, Adams' anvil surface) can engage tissue does not mean that it can acquire tissue. Contrary to the Advisory Action's assertion, there is no structure in Adams that teaches that elements 10 and 17 acquire tissue and the Examiner has failed to cite anything to support his position. Absent some showing that Adams' anvil "acquires" tissue as that term is properly construed, the rejection of Claim 29 must be withdrawn for failure to make out a *prima facie* case of obviousness.

Applicant further argued in the Rule 116 Amendment that neither Adams nor Deem teach tissue acquisition members "including a tissue receiving cavity sized to receive a fold of stomach tissue." The Office Action does not cite to any structure that it contends satisfies this structural limitation, so Applicant finds it problematic to guess as to what the Office Action is referring when it contends that Deem teaches this claim limitation. Certainly there is no "cavity" in the cartridge assemblies **170** and **190** relied upon by the Office Action that would meet this claim limitation. In the assembly 170 shown in Figure 9A, there is no structure that would satisfy the "first and second acquisition members" and, even if there were, there are no "cavities" that are part of any tissue acquisition members where the cavities are sized to receive a fold of stomach tissue. Thus, Applicant has identified a third reason for withdrawing the rejection of Claim 29.

Moreover, the use of a staple in both the left and right halves of the Deem apparatus shown above strongly teach away from having pivotable first and second halves since it would serve no purpose here. Employing Adams' stapling mechanism would be incompatible with Deem's tissue acquisition since there is no teaching in either reference that would allow Deem's longitudinal tissue acquisition with Adams' circumferential stapling. Since the Office Action's rejection requires the circumferential stapling of Adams, then it is incumbent upon the Office Action to explain how Deem must be re-engineered to acquire tissue because there is nothing on the face of either references that suggest how Deem to could be reconfigured to work with Adams' circumferential stapler. Because the rejection unduly relies on the Applicant's teachings to formulate the proposed combination of Deem and Adams, Applicant respectfully submits that a *prima facie* case of obviousness has not been established and that the claims must be reconsidered in light of what the prior art references **actually suggest** to one of ordinary skill in the art without the benefit of the Applicant's present teaching.

The Advisory Action appears to concede that the Final Office Action failed to discuss the limitations of Claim 35, identifying those elements for the first time in the Advisory Office Action in response to the Rule 116 Amendment. If the rejection was spelled out in the Advisory Action after final rejection, it is unclear how Applicant may properly address the rejection. It would seem reasonable to expect that an Applicant be provided an opportunity to respond to a rejection in a non-final office action rather than be informed of the rejection for the first time in an advisory action.

Nevertheless, the Office Action contends that Deem Figures 9A-9B shows the necessary structure. Claim 35 includes the following limitation:

*a first tissue receiving cavity disposed between the stapling member and the longitudinal hinge, and a second tissue receiving cavity disposed between the anvil member and the longitudinal hinge, the first and second tissue receiving cavities coupled to a vacuum source*

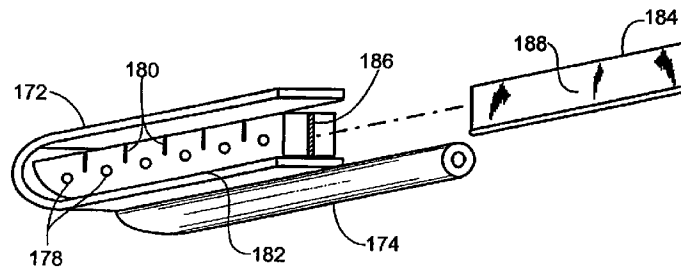


Figure 9B of the Deem reference is shown above. Even if the Deem reference is modified as suggested by the Office Action to include the circumferential stapling mechanism of Adams, it is still unclear to Applicant how the claim limitation could be met. There does not appear to be any location for the "hinge" that would make the limitation read on the modified device, since it would seem necessary that the hinge in order to function as the Examiner proposes would need to be below the anvil 182. If the hinge was below the anvil 182, then there could be no "second tissue receiving cavity disposed between the anvil member and the longitudinal hinge." The problem with even trying to guess what the Examiner was envisioning is that the rejection was explained for the first time in the Advisory Action, and then it was given only a single, conclusory sentence of explanation. Applicant contends that this cannot constitute a *prima facie* case of obviousness and must be withdrawn.

Applicant has shown that the rejection of the claims do not meet the requirements as set forth in the MPEP, and are properly stricken. There being no other outstanding rejections, Applicant contends that the claims should be passed to allowance and Applicant be notified of same at the earliest opportunity.